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10/518,822	01/13/2005	Mitsuru Horiba	ADACHI P265US	9877

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
12/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,822	HORIBA ET AL.	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on September 11, 2009, Applicant amended claims 6, 10, and 11.

2. In the non-final rejection of June 17, 2009, Examiner objected to claim 10 for being an improper multiple dependent claim since claim 10 depended on previous multiple dependent claim 9. Applicant amended claim 10 to only depend upon one of claims 6-8. Objection is withdrawn.

3. Examiner rejected claims 6 and 11 under 35 USC 112, 1st paragraph, for new matter with regards to the limitation "sufficiently small in size as to be inserted into a blood vessel". Applicant amended said claims. Rejection is withdrawn.

4. Examiner rejected claim 11 under 35 USC 112, 2nd paragraph, for insufficient antecedent basis for the term "the target region". Applicant amended the term to be "a target region". Rejection is withdrawn.

5. Currently, claims 6-18 are under examination.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "injectant storage that is located at the **distal end**" must be shown or the feature(s) canceled from the claim(s). In the reply of September 11, 2009, Applicant provided a new drawing of Figure 3B in which it appears that the

injectant storage [58] is located at the **proximal end** of the catheter, not the distal end, as claimed and as in the specification (paragraph [0009]). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 6-9, 11, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al (US 5,536,251), and further in view of Kratsch et al (US 5,478,350), Cornelius et al (US 5,382,234), and Altman (US 6,102,887).

In regards to claim 6, Evard et al teaches a catheter (Figures 5A-6D, device [110]) comprising:

a. an outer tube (outer shaft [66])

b. a first inner tube (inner shaft [72]) located within the outer tube [66] and containing a forceps mechanism (jaw extensions [78][80] with lever [94])

c. a second inner tube (inner sleeve [112]) also located within the outer tube [66] containing an injection mechanism (delivery tube [120] with needle [124])

d. the forceps mechanism having a first handling portion [94] at the proximate end (Figure 5A) and a grasping portion (jaws [82][84]) at the distal end (Figure 5B), the grasping portion being configured to open and close in conjunction with manipulation at the first handling portion, and being capable of holding the target region accessed by the catheter (column 8, lines 46-51)(column 9, lines 7-10)

e. the injection mechanism having a second handling portion (actuation button [140]) at the proximate end, and an injection needle [124] at the distal end, the injection needle being configured to be moved forward into a position to so as to protrude from the distal end (Figures 6B-6C), and to be moved back into a retracted position stored inside of the distal end (Figure 6D), and the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (column 10, lines 8-13)

Evard et al does not teach that the outer tube [66] is of a size such that the distal end is insertable into a blood vessel, since Evard et al only teaches the insertion of the outer tube into the chest wall and into the thoracic cavity through an intercostal space between two adjacent ribs (column 13, lines 42-46). However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the outer tube of Evard et al to be smaller in size for insertion into a blood vessel, since it has been held that merely changing the size or proportion of a device is not sufficient to patentably distinguish over the prior art. *In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955)*; *In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)*. A person having ordinary skill in the art at the time the invention was made would know how to scale down the outer tube of the catheter of Evard et al for the purposes of providing treatment to a blood vessel.

In further regards to claim 6, Evard et al does not teach an operating linkage constrained within the first inner tube in a closed position. Kratsch et al teaches a forceps mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Evard et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged

with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In further regards to claim 6, Evard et al does not teach a guidewire tube located within the outer tube parallel to the forceps mechanism and the injection mechanism, the guidewire tube accommodating a guidewire. Cornelius et al teaches a catheter (Figures 1-2), wherein a guidewire tube (first tubular member [18]) is located within an outer tube (sleeve [30]) parallel to an injection mechanism (inflation fluid provided in a second tubular member [22]) and the guidewire tube accommodates a guidewire (guidewire, not shown). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter, of Evard et al, with a guidewire tube accommodating a guidewire, as taught by Cornelius et al, as the guidewire tube will allow a guidewire to extend therethrough the catheter (column 7, lines 8-11) and the guidewire will establish a path through a target region of the patient's body before the catheter is inserted into the body (column 1, lines 26-33).

In regards to claim 6, Evard et al is silent about whether the injection mechanism communicates with an injectant storage that is located at the distal end such that manipulation at the proximate end pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to the injection needle. Altman teaches a catheter (Figures 4A-4B), wherein an injection mechanism communicates with an injectant storage (delivery chamber [406]) that is located at a distal end such that manipulation at the proximate end pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to an injection needle (needle [410]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter, of Evard et al, with an injectant storage that

forces a pressurized flow of injectant into the injection needle, as taught by Altman, as such will provide an efficient and rapid means for delivering therapeutic agent to the patient's body. The advancement of the needle into the patient's body will trigger the injectant storage to deliver pressurized therapeutic agent into the body (column 5, lines 64-67 to column 6, lines 1-9)(column 6, lines 40-50).

In regards to claim 7, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al teaches that the forceps mechanism [78][80][94] is configured to bias the grasping portion [82][84] toward a direction to close the grasping portion with force of a spring (spring, not shown) (column 8, lines 52-54)(column 9, lines 7-10).

In regards to claim 8, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, the current embodiment of Evard et al (Figures 5A-6D) does not teach that the forceps mechanism comprises a lock device that prevents the grasping portion opening and closing. Evard et al teaches another embodiment (Figures 1-2B) in which a forceps mechanism (jaws [30][32] with actuator [36]) comprises a lock device (notched extensions [42]) that prevents a grasping portion opening and closing (column 7, lines 37-46). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Evard et al (Figures 5A-6D), Kratsch et al, Cornelius et al, and Altman, with a lock device, as taught by Evard et al (Figures 1-2B), as the lock device will provide ratcheted locking of the forceps mechanism in order to maintain the grasping portion in a closed position in order to avoid unnecessary opening and actuation of the grasping portion (column 7, lines 42-46).

In regards to claim 9, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al teaches that the injection mechanism is configured to bias the injection needle [124] toward a direction to move back the injection needle with the force of a spring (spring [164]) (column 10, lines 14-27).

In regards to claim 11, Evard et al teaches a catheter (Figures 5A-6D, device [110]) comprising:

a. an outer tube (outer shaft [66])

b. a first inner tube (inner shaft [72]) located within the outer tube [66] and containing a forceps mechanism (jaw extensions [78][80] with lever [94]) having a first handling portion [94] at the proximate end (Figure 5A) and a grasping portion (jaws [82][84]) at the distal end (Figure 5B), and being capable of holding the target region accessed by the catheter (column 8, lines 46-51)(column 9, lines 7-10)

c. a second inner tube (inner sleeve [112]) located within the outer tube [66] containing an injection mechanism (delivery tube [120] with needle [124]) having a second handling portion (actuation button [140]) at the proximate end and an injection needle [124] at the distal end, the injection needle being configured to be moved forward into a position to so as to protrude from the distal end (Figures 6B-6C), and to be moved back into a retracted position stored inside of the distal end (Figure 6D), and the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (column 10, lines 8-13)

Evard et al does not teach that the outer tube [66] is of a size such that the distal end is insertable into a blood vessel, since Evard et al only teaches the insertion of the outer tube into the chest wall and into the thoracic cavity through an intercostal space between two adjacent ribs (column 13, lines 42-46). However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the outer tube of Evard et al to be smaller in size for insertion into a blood vessel, since it has been held that merely changing the size or proportion of a device is not sufficient to patentably distinguish over the prior art. *In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955)*; *In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)*. A person having ordinary skill in the art at the time the invention was made would know how to scale down the outer tube of the catheter of Evard et al for the purposes of providing treatment to a blood vessel.

In further regards to claim 11, Evard et al does not teach an operating linkage constrained within the first inner tube in a closed position. Kratsch et al teaches a forceps mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Evard et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged

with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In further regards to claim 11, Evard et al does not teach a guidewire tube located within the outer tube parallel to the forceps mechanism and the injection mechanism, the guidewire tube accommodating a guidewire. Cornelius et al teaches a catheter (Figures 1-2), wherein a guidewire tube (first tubular member [18]) is located within an outer tube (sleeve [30]) parallel to an injection mechanism (inflation fluid provided in a second tubular member [22]) and the guidewire tube accommodates a guidewire (guidewire, not shown). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter, of Evard et al, with a guidewire tube accommodating a guidewire, as taught by Cornelius et al, as the guidewire tube will allow a guidewire to extend therethrough the catheter (column 7, lines 8-11) and the guidewire will establish a path through a target region of the patient's body before the catheter is inserted into the body (column 1, lines 26-33).

In regards to claim 11, Evard et al is silent about whether the injection mechanism communicates with an injectant storage that is located at the distal end such that manipulation at the proximate end pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to the injection needle. Altman teaches a catheter (Figures 4A-4B), wherein an injection mechanism communicates with an injectant storage (delivery chamber [406]) that is located at a distal end such that manipulation at the proximate end pressurizes the injectant storage and forces a flow of the injectant from the injectant storage and to an injection needle (needle [410]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter, of Evard et al, with an injectant storage that

forces a pressurized flow of injectant into the injection needle, as taught by Altman, as such will provide an efficient and rapid means for delivering therapeutic agent to the patient's body. The advancement of the needle into the patient's body will trigger the injectant storage to deliver pressurized therapeutic agent into the body (column 5, lines 64-67 to column 6, lines 1-9)(column 6, lines 40-50).

In regards to claim 12, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al teaches a spring (spring, not shown) having a spring force wherein the spring force maintains the forceps mechanism [78][80][94] in the closed state (column 8, lines 52-54)(column 9, lines 7-10).

In regards to claim 16, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al teaches a deflectable spring (spring [164]) which maintains the needle [124] of the injection mechanism in a retracted state within the second inner tube [112] (column 10, lines 14-27).

9. Claims 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al, Kratsch et al, Cornelius et al, and Altman, as applied to claims 11 and 12 above, and further in view of Clement et al (US 5,350,384).

In regards to claim 13, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al teaches that the spring force is overcome by an operator influencing the first handling portion [94] (column 8, lines 52-54); however, Evard et al is silent about whether the spring is compressed to move the grasping portion [82][84] to the open state. Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a spring (compression spring [44]) is

compressed to move a grasping portion (jaws [32]) to an open state (Figure 6B) (column 4, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the spring of the forceps mechanism, of the modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, to compress to move the grasping portion to an open state, as taught by Clement et al, as a preferential obvious design choice to the user, as compression of the spring will provide a suitable and efficient means for moving the grasping portion to the open state (column 4, lines 5-10).

In regards to claim 14, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, Altman, and Clement et al, Evard et al does not teach a linkage of the grasping portion [82][84]. Kratsch et al teaches an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) that is constrained within a tube (sleeve [64]) in a closed position (Figure 16) and is displaced outside of the tube to facilitate a complete lateral expansion of the linkage and a fully open position of the grasping portion [58][59] (Figure 15). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Evard et al, Kratsch et al, Cornelius et al, Altman, and Clement et al, with an operating linkage that is constrained within the first inner tube in a closed position and displaced outside of the first inner tube in an open position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In regards to claim 15, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, Altman, and Clement et al, the current embodiment of Evard et al (Figures 5A-6D) does not teach that the forceps mechanism comprises a lock device that prevents the grasping portion opening and closing. Evard et al teaches another embodiment (Figures 1-2B) in which a forceps mechanism (jaws [30][32] with actuator [36]) comprises a lock device (notched extensions [42]) that prevents a grasping portion opening and closing (column 7, lines 37-46). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Evard et al (Figures 5A-6D), Kratsch et al, Cornelius et al, Altman, and Clement et al, with a lock device, as taught by Evard et al (Figures 1-2B), as the lock device will provide ratcheted locking of the forceps mechanism in order to maintain the grasping portion in a closed position in order to avoid unnecessary opening and actuation of the grasping portion (column 7, lines 42-46).

In regards to claim 18, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, neither Evard et al nor Kratsch et al teaches that the linkage comprises a four-bar mechanism. Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a linkage comprises a four-bar mechanism (jaws [32] and spreader links [38]) (Figures 6A-6B). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the linkage, of the forceps mechanism of the modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, with a four-bar mechanism, as taught by Clement et al, as the four-bar mechanism will allow the grasping portion to laterally spread in the open position for clamping around a patient's body portion and laterally compress in the closed position for storage (column 3, lines 59-68).

10. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al, Kratsch et al, Cornelius et al, and Altman, as applied to claims 6 and 16 above, and further in view of Haughton et al (US 5,376,075).

In regards to claim 10, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al does not teach a locking device that forbids the injection needle [124] moving back. Haughton et al teaches an injection mechanism (Figures 6-10), wherein a locking device (stud [146] in slots [150][152]) maintains a needle in the extended position. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the injection mechanism, of the modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, with a locking device, as taught by Haughton et al, as the locking device will retain the needle in the extended position during insertion of the catheter into a blood vessel (column 6, lines 48-59).

In regards to claim 17, in a modified catheter of Evard et al, Kratsch et al, Cornelius et al, and Altman, Evard et al does not teach a piston and a cylinder for overcoming a bias of the deflectable spring [164] that is configured to retract the needle [124] and a locking device that is actuatable to maintain the needle in a desired position. Haughton et al teaches an injection mechanism (Figures 6-10), wherein a spring (spring [148]) biases an injection needle (trocar [130]) of the injection mechanism toward a direction to move back the injection needle (Figures 8-9). Haughton et al also teaches that the injection mechanism further comprises a piston (stud [146]) and a cylinder (hub [142]) for overcoming the bias of the spring [148] with a locking device (stud [146] in slots [150][152]) for maintaining the needle in the extended position (i.e.

forbids the needle moving back). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the injection mechanism, of the modified catheter of Evard et al and Kratsch et al, with a piston, cylinder, and locking device, as taught by Haughton et al, as the piston, cylinder, and locking device will retain the needle in the extended position during insertion of the catheter into a blood vessel, and the spring will urge the needle inwardly away from its extended position in order to enclose the sharpened end of the needle after use (Abstract)(column 6, lines 39-59).

Response to Arguments

11. Applicant's arguments, see pages 12-13, filed on September 11, 2009, with respect to the rejection(s) of claim(s) 6-9, 11, 12, and 16 under Evard et al, in view of Kratsch et al, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Evard et al, Kratsch et al, Cornelius et al, and Altman, based on the insertion of subject matter (guidewire tube with guidewire, injectant storage) not previously presented in the claims into independent claims 6 and 11. The previous combination of Evard et al and Kratsch et al does not teach the newly inserted subject matter of the claims.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
12/8/2009

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767